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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,485	04/03/2006	Kerang Jiang	P70789US0	9139
136 7590 11/18/2009 JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004				
EXAMINER HENDERSON, RYAN N				
ART UNIT		PAPER NUMBER		
3739				
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11/18/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,485

Applicant(s)

JIANG ET AL.

Examiner

RYAN HENDERSON

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 6, 2009, Reply to Amendment.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 7 and 8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ ~~Notice of Informal Patent Application~~
- 6) ☐ Other: _____

DETAILED ACTION

Notice of Amendment

1. The Amendment filed October 6, 2009 has been entered. Claims 3, 5, 6, 9 and 10 have been canceled and claims 1, 2, 4, 7 and 8 have been amended and remain pending in the application. The objection to claims 1-10 and the previous 35 USC 112 First and Second Paragraph rejections have been withdrawn in light of applicant's amendments.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (US Patent No. 5,050,585) in view of Jones (US Patent No. 5,386,817).

In regard to claim 1, Takahashi discloses an endoscope system (**Fig. 1**) with a disposal sheath (**11**), including an endoscope (**1**) which can be reused for many times and a disposal sheath (**Par. 4, Lines 40-45**);

wherein a capsule (**10**) covers the outside of the endoscope as a part of the disposal sheath, connects with a disposal channel which is inserted into the

endoscope channel (9), both the anterior ends of the capsule and the disposal channel are connected and joined **(the capsule and disposal channel meet at the distal end)**;

after passing through the endoscope channel, the disposal channel is positioned in a three-way sealing cap (14) via a guide tube (17);

after use, the channel orifice of the disposal channel can be heated and melted and cut off by a heat fusion forceps **(this is an intended use limitation where the disposal channel can be melted and cut off by a heat fusion forceps)**.

Takahashi fails to teach of the fluid-air channel being set outside of the endoscope, wherein the capsule covers the outside of the endoscope joining a jet channel and fluid-air channel via an end cap. Takahashi also fails to teach of the capsule containing a locking ring and the disposal channel being positioned in a three-way sealing cap via a guide tube.

Jones teaches of a sheath **(Figs. 5-6, #36)** for an endoscope that comprises tubes **(90A, 90B, 90C)** that run parallel, but exterior to the endoscope within the sheath that provide fluid and air to clean the distal end of the endoscope **(Par. 8, Lines 14-27)**. The sheath contains an end cap **(40)** at the distal end thereof, wherein the tubes run from the proximal end of the sheath to the distal end of the end cap. Attached to the distal end of tubes **(90A and 90B)** are spray ports **(72)** to provide spray cleaning access to the exterior of the window **(48)**, **Par. 6, Lines 58-60**. Jones also teaches of a locking ring **(34)** attached to the proximal end of the sheath which forms a friction attachment between the sheath and the endoscope **(Par. 5, Lines 53-59)**.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the disposal sheath of Takahashi with the locking ring and fluid/suction tubes of Jones to prevent the sheath from slipping down the flexible portion toward the distal end of the endoscope (**Par. 5, Lines 56-59**). Allowing the tubes (**90A, 90B, 90C**) to be carried exterior to the endoscope prevent them from becoming contaminated and avoids the necessity of cleaning and sterilizing the endoscope (**Par. 8, Lines 3-13**).

In regard to claim 2, Takahashi as modified by Jones teaches of the endoscope system with a disposal sheath, according to the claim 1, characterized in that the end cap is made of a transparent material (**Jones teaches of the end cap being made of plexi-glass which is transparent**), its inner end face's shape coincides with the anterior end face of the endoscope body, while the capsule is strained (**after the sheath is pulled all the way over the endoscope and the locking ring is provides a frictional attachment to the endoscope, the endoscope forms a tight fit within the end cap**).

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (US Patent No. 5,050,585) in view of Jones (US Patent No. 5,386,817), as applied to claim 1, and further in view of Wortrich (US Patent No. 5,263,939).

In regard to claim 4, Takahashi as modified by Jones teaches of the endoscope system with a disposal sheath, according to the claim 1, but does not expressly teach of the locking ring having upper and lower oblique teeth and the handle can make the capsule fix or loose with respect to the endoscope.

Wortrich teaches of a clamp (**Fig. 5-6, #30**) for holding a laparoscopic cannula. The clamp has four inner walls (**44**) that come in contact and hold the medical device firmly in place. The surgeon is able to make the grip looser or tighter by adjusting where the second arm (**33**) engages with the teeth (**36**) on the first arm (**32**).

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide Takahashi with the locking ring of Jones modified by the clamp of Wortrich to provide the physician a way to easily adjust how tight the disposal sheath compresses against the endoscope.

4. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahashi (US Patent No. 5,050,585) in view of Jones (US Patent No. 5,386,817), as applied to claim 1, and further in view of Akiba (US Patent No. 6,117,070)

In regard to claim 7, Takahashi as modified by Jones teaches of the endoscope system with a disposal sheath, according to the claim 1, but fails to teach of the three-way sealing cap containing three elastic sealing orifices and the inner diameter of the three-way sealing cap being less than the outer diameter of the disposal channel.

Akiba teaches of a plug device for an endoscopic instrument channel. The plug comprises three sealing orifices **(25, 28, 29)** that can be seen in Figs. 4 and 7. Akiba teaches of the orifices being slightly greater or smaller than the instrument being inserted through **(Col. 8, Lines 13-28)**. When the guide tube **(17)** of Takahashi is advanced through the plug device of Akiba, the orifices will be effectively sealed.

It would have been obvious to one of ordinary skill in the art at the time of the invention to provide the disposal sheath of Takahashi with the plug device of Akiba to effectively seal the exit of the endoscope channel to prevent the endoscope from being contaminated with blood or mucus from within the body.

In regard to claim 8, Takahashi teaches of the endoscope system with a disposal sheath, according to the claim 7, characterized in that the outer diameter of the guide tube is larger than the inner orifice of the three-way sealing cap **(see rejection to claim 7)** and the inner diameter of the guide tube is less than the outer diameter of the disposal channel **(see Fig. 3 of Takahashi)**; the guide tube can be sheathed in the three-way sealing cap **(the guide tube is inserted into the sealing cap, see rejection to claim 7)**, in advance, for sheathing the disposal channel in; *the disposal channel instantly is contracted and fixed, while the guide tube is pulled out from the three-way sealing cap, the disposal channel is fixed by the second elastic sealing orifice, to make the posterior end put on right position of the three-way sealing cap (this is an intended use limitation, wherein when the guide tube is withdrawn from the sealing cap the disposal channel would be fixed within the sealing cap).*

Response to Arguments

5. Applicant's arguments with respect to claims 1, 2, 4, 7 and 8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **RYAN HENDERSON** whose telephone number is (571)270-1430. The examiner can normally be reached on M-F 7:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571)272-4764. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. H./
Examiner, Art Unit 3739
November 13, 2009

/Linda C Dvorak/
Supervisory Patent Examiner, Art
Unit 3739